

46851-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

DEC -- 2 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Lewis Ward  
Certol International, LLC  
6120 E. 58<sup>th</sup> Avenue  
Commerce City, CO 80022

Subject: Omni II™ Concentrated Surface Disinfectant and Holding Solution  
EPA Registration No. 46851-1  
Amendment Date: June 28, 2010  
EPA Receipt Date: July 2, 2010

Dear Mr. Ward

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable with conditions.

**Proposed Amendment**

- Add disinfectant claim against *Staphylococcus aureus*- MRSA HA and CA
- Add alternate brand name, ProSpray C-60

**Conditions**

Revise the label as follows:

- 1.) The signal word, DANGER, must appear in a larger font, preferably the same font as the claim, Tuberculocidal, Virucidal, Bactericidal, Fungicidal above the EPA Registration Number.
- 2.) The phrase, Keep Out of Reach of Children, must appear directly above the signal word, DANGER such that it is in accordance with the Label Review Manual.
- 3.) The HIV-1 directions are incomplete, you must add the following text to appear above the "Special Instructions" statement:

**\*KILLS HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus

Type-1 HIV-1 (associated with AIDS).

**CONCURRENCES**

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4.) Delete the second heading, "User Safety Recommendations." The information under this heading must be incorporated into the "User Safety Requirements" section.

5.) Revise the 1<sup>st</sup> paragraph under the "Directions for Use" by deleting the 2<sup>nd</sup> and 3<sup>rd</sup> statements and placing them under the "Soak/Decontamination" directions. The directions and heading must be revised to read as follows:

**Medical and Dental Instrument Soak/Decontamination:** Thoroughly clean surface of medical and dental instruments that will be disinfected and rough dry. Immerse instruments in a 1:32 use solution of Omni II for 10 minutes. Rinse articles thoroughly with potable water and pat dry. Sterilize instruments prior to use. The efficacy of the solution is compromised in the presence of organic matter. Prepare a fresh solution daily or more often if it becomes diluted or soiled.

6.) Revise the "Ultrasonic Cleaning" heading and directions to read as follows:

**Ultrasonic Bath Disinfection:** Thoroughly clean surface of noncritical medical and dental objects compatible with ultrasonic cleaning units. Prepare fresh 1:32 use solution of Omni II in bath chamber. Place objects into unit and operate for a 10 minutes according to manufacturer's directions. Remove objects and wash with sterile water or allow to air dry. Prepare fresh solution for each use.

7.) Revise the 1<sup>st</sup> statement under the "Cleaning" directions by adding the phrase, "Prepare 1:32 use solution of Omni II ..."

8.) Revise the "Hard Surface Disinfection" heading and directions to read as follows:

**Hard Nonporous Surface Disinfection:** Preclean surfaces as prescribed above. Apply 1:32 use solution of Omni II to hard nonporous surfaces such as floors, walls, counters, tables with mop, sponge, spray, or cloth. Surfaces must remain wet for 10 minutes. Allow to air dry or remove excess with clean cloth or sponge. Prepare a fresh solution daily or more often if it becomes diluted or soiled.

9.) Revise the "Pesticide Storage" statement to read "Store in original container in a area inaccessible to persons unfamiliar with its use."

10.) The "Container Disposal" statements must be updated to be in compliance with PR Notice 2007-4 by stating "Non-refillable container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill container ¼ full with water and recap. Shake for 10 seconds. Discard rinsate in accordance with Pesticide Disposal instructions. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by procedures approved by state and local authorities.

CONCURRENCES

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**Data Summary**

Data Requirement	Means of Support	Status
AOAC Use Dilution Method -MRSA HA	Submitted study, MRID 481408-01	Acceptable, RTU in 10 min
AOAC Use Dilution Method -MRSA CA	Submitted study, MRID 481408-02	Acceptable, RTU in 10 min

**General Comments**

The alternate brand name, ProSpray C-60, is acceptable.

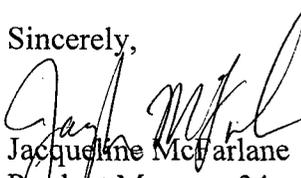
A stamped accepted label is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have further questions concerning this letter, please contact me at 703-308-6416 or by email at [Campbell-mcfarlane.jacqueline@epa.gov](mailto:Campbell-mcfarlane.jacqueline@epa.gov) or Killian Swift at (703) 308-6416 or by email at [swift.killian@epa.gov](mailto:swift.killian@epa.gov). When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Jacqueline McFarlane  
 Product Manager 34  
 Regulatory Management Branch II  
 Antimicrobials Division (7510P)

Enclosure: Stamped Label  
 Efficacy Data Evaluation

**CONCURRENCES**

SYMBOL	SURNAME	DATE						



First Aid

IF IN EYES: Hold eye open and flush slowly and gently with water for 15 minutes. Remove contact lenses if present after the first 5 minutes and then continue flushing. Call a Poison Control Center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

IF SWALLOWED: Call a Poison Control Center or doctor immediately for treatment advice. If a person is unconscious, call 911 or a doctor. Do not induce vomiting unless told by a Poison Control Center or doctor. Do not give any liquid to an unconscious person.

IF INHALED: Move person to fresh air. If persons are not breathing, call 911 or a doctor, and then give artificial respiration preferably mouth to mouth if possible. Call a Poison Control Center or doctor for further treatment advice. In case of an emergency or for a referral, call 1-800-FREE-811. Have the product container on hand with you when calling a Poison Control Center or doctor.

IF GETTING ON OR NEAR YOUR FACE: Wash your face immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR EYES: Wash your eyes immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR MOUTH: Wash your mouth immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR THROAT: Wash your throat immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR NOSE: Wash your nose immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR EARS: Wash your ears immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR HAIR: Wash your hair immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR CLOTHING: Wash your clothing immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR SHOES: Wash your shoes immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR SKIN: Wash your skin immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR FACE: Wash your face immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR EYES: Wash your eyes immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR MOUTH: Wash your mouth immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR THROAT: Wash your throat immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR NOSE: Wash your nose immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

IF GETTING ON OR NEAR YOUR EARS: Wash your ears immediately with plenty of water. Call a Poison Control Center or doctor for treatment advice.

# Omnii II™

## Concentrated Surface Disinfectant and Holding Solution

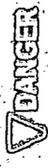
### Lemon Scent

### Tuberculocidal, Virucidal, Bactericidal, Fungicidal

Active Ingredients	9.0%
o-chlorophenol	1.0%
o-terryl-p-chlorophenol	90.0%
Inert Ingredients	100.0%
Total	

Contents: 1 Quart (32 oz - 845 ml)  
Dilutes to make 8 gallons of active solution.

EPA Reg. No. 4655-1  
EPA Est. No. 46551-00-008



Recorder No. 01N222  
Lot Number printed on container

Keep Out of Reach of Children. See other panels for additional Precautionary Statements.

ACCEPTED with COMMENTS  
EPA Letter Dated:

DEC 2 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered for the pesticide use as shown on the label. Registered under EPA Reg. No.

46851-1

01N222/UL13 15/03

Proposed Label

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**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION:** Avoid contact with skin, eyes, nose, mouth, or clothing. Wash hands thoroughly with soap and water after use. Do not use on surfaces that are porous or absorbent. Do not use on surfaces that are painted or coated. Do not use on surfaces that are made of metal, plastic, or wood. Do not use on surfaces that are made of stone or masonry. Do not use on surfaces that are made of fabric or paper. Do not use on surfaces that are made of leather or vinyl. Do not use on surfaces that are made of rubber or latex. Do not use on surfaces that are made of glass or ceramic. Do not use on surfaces that are made of enamel or chrome. Do not use on surfaces that are made of brass or copper. Do not use on surfaces that are made of aluminum or steel. Do not use on surfaces that are made of zinc or tin. Do not use on surfaces that are made of nickel or cobalt. Do not use on surfaces that are made of chromium or manganese. Do not use on surfaces that are made of iron or nickel. Do not use on surfaces that are made of titanium or zirconium. Do not use on surfaces that are made of niobium or tantalum. Do not use on surfaces that are made of hafnium or zirconium. Do not use on surfaces that are made of yttrium or cerium. Do not use on surfaces that are made of lanthanum or praseodymium. Do not use on surfaces that are made of neodymium or europium. Do not use on surfaces that are made of gadolinium or terbium. Do not use on surfaces that are made of dysprosium or holmium. Do not use on surfaces that are made of erbium or thulium. Do not use on surfaces that are made of ytterbium or lutetium. Do not use on surfaces that are made of scandium or yttrium. Do not use on surfaces that are made of cerium or lanthanum. Do not use on surfaces that are made of praseodymium or neodymium. Do not use on surfaces that are made of europium or gadolinium. Do not use on surfaces that are made of terbium or dysprosium. Do not use on surfaces that are made of holmium or erbium. Do not use on surfaces that are made of thulium or ytterbium. Do not use on surfaces that are made of lutetium or scandium.

**PRECAUTIONARY STATEMENT - Hazardous to Humans and Domestic Animals:** DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if inhaled, swallowed, or absorbed through skin. Do not get in eyes, on clothing, or in mouth. Avoid breathing mist. Wear goggles, safety glasses or face shield, protective clothing, long-sleeved shirt, long pants and shoes and water resistant gloves.

**USER SAFETY REQUIREMENTS:** Follow manufacturer's instructions for cleaning and maintaining PPE (Personal Protective Equipment). If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**First Aid:** If swallowed, do not induce vomiting. If in eyes, flush with water for at least 15 minutes. If on skin, wash with soap and water. If inhaled, move to fresh air. If symptoms persist, call a doctor. If on clothing, remove and wash separately.

